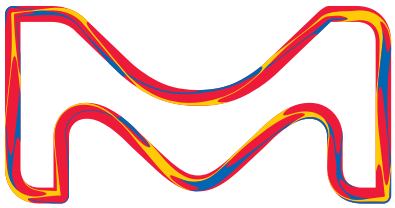
Blood Typing Monoclonal Antibodies FFMU

Blood typing intermediates for further manufacturing use



The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Millipore®

Preparation, Separation, Filtration & Monitoring Products


B. Braun
Biotech
International
DCU

We are your partner for monoclonal blood typing antibodies

Merck is one of the leading providers of monoclonal antibodies to the blood typing market. Our large portfolio of standardized antibody intermediates for further manufacturing use allows manufacturers to create and manufacture a wide variety of blood typing reagents and devices. Our ISO-certified, FDA-licensed manufacturing facilities ensure the quality of these antibodies to meet global regulatory requirements.

Product Directory

Blood Typing Intermediates

Millipore® portfolio of blood typing intermediates for further manufacturing use (FFMU) are standardized cell culture supernatants from cell lines expressing human or murine monoclonal antibodies. These FFMU intermediates are for use in formulating finished blood typing reagents or devices. By dilution, blending (where appropriate) and chemical additions, manufacturers can formulate their own finished reagents or devices with reactivity profiles suitable for their specific applications. The potency of each batch is carefully controlled to match that of an internal reference batch. All FFMUs contain 0.1% (w/v) sodium azide as a preservative.

ABO Intermediates FFMU

Anti-A (clone BIRMA-1) – JH

The BIRMA-1 antibody reacts strongly with all common forms of the A antigen, including A_2B. When used at appropriate concentrations, it will directly agglutinate most examples of A_x. It has the benefit of not agglutinating red cells classified as having the B(A) phenomenon, nor of agglutinating unmodified or enzyme treated B or O red cells. It is a proven raw material for the manufacture of Anti-A reagents and devices.

Anti-B (clone LB-2) – JM

This antibody reacts strongly with all common forms of the B antigen. It has the benefit of not agglutinating unmodified or enzyme treated A or O red cells, or A_1 red cells with the "Acquired B" antigen. JM does not have the same capacity for dilution as JE, due to formation of a cryoprecipitate upon further concentration. It is a proven raw material for the manufacture of Anti-B reagents and devices.

Anti-B (clone ES-4) – JE

ES-4 gives strong reactions with all red cells displaying regular forms of the B antigen. In common with the polyclonal Anti-B found in human group A plasma, this antibody agglutinates A_1 red cells that exhibit the "Acquired B" phenomenon. The major application for this FFMU is as a constituent of a blended Anti-A+B reagent. VK (clone ES-15) is an excellent blending partner for this purpose.

Anti-A(B) (clone ES-15) – VK

This antibody directly agglutinates group A red cells, including the weaker subgroups. It is particularly effective in detection of the weaker forms of A_x. It reacts with B cells to a lesser degree. It can be blended with an Anti-B FFMU such as JM or JE to formulate an Anti-A+B reagent.

All the ABO FFMUs are diafiltered against phosphate buffered saline and are licensed with the US FDA under shared manufacturing agreements.

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-A	Murine IgM	BIRMA-1	7.2 ± 0.5	1–11 mg/mL	24 months	1 L Bulk	**JH-1L-BK**
						10 L Bulk	**JH-10L-BK**
Anti-B	Murine IgM	LB-2	7.2 ± 0.5	3–15 mg/mL	24 months	1 L Bulk	**JM-1L-BK**
						10 L Bulk	**JM-10L-BK**
Anti-B	Murine IgM	ES-4	6.0 ± 0.5	6–17 mg/mL	24 months	1 L Bulk	**JE-1L-BK**
						10 L Bulk	**JE-10L-BK**
Anti-A(B)	Murine IgM	ES-15	7.2 ± 0.5	3–15 mg/mL	24 months	1 L Bulk	**VK-1L-BK**
						10 L Bulk	**VK-10L-BK**

Anti-D Intermediates FFMU

In the opinion of most experts in the field of transfusion science, the ideal anti-D for typing patients is one that does not react with D category VI cells. Our four IgM Anti-D antibodies do not detect these D^{VI} cells and are therefore good candidates for use in formulating anti-D reagents for patient testing.

For typing donor blood, detection of D category VI red cells is required. FFMU KK, IgG anti-D made from clone MS-26, reacts with these cells and can be blended with any of the Millipore® IgM FFMUs to create a product that detects most D, weak D and partial D phenotypes.

All Millipore® Anti-D FFMU are diafiltered against phosphate buffered saline, and except for JV RUM-1, are licensed with the US FDA under shared manufacturing agreements.

Anti-D IgM (clone RUM-1) – JV

RUM-1 is the most avid of the four Millipore® IgM Anti-D FFMU intermediates. The fine specificity of this antibody is ideal for the manufacture of an IgM only Anti-D reagent for typing patient samples. RUM-1 is the international Anti-D standard assigned by the World Health Organization (WHO).

Anti-D IgM (clone MS-201) – KU

The antibody from MS-201 has the identical fine specificity as RUM-1. It is slightly less avid in its native state.

Anti-D IgM (clone MAD-2) – JT

MAD-2 was the first monoclonal Anti-D to be licensed by the US FDA. This antibody does not directly agglutinate some examples of weak D or partial D cells.

Anti-D IgM (clone TH-28) – KP

The antibody from clone TH-28 has a capability for detecting weak and partial D phenotypes that are greater than that of MAD-2 and less than that of RUM-1 or MS-201.

Anti-D IgG (clone MS-26) – KK

This antibody reacts with D^{VI} red cells. Since it is IgG, a sensitization technique is required to induce agglutination; e.g., anti-human globulin, enzyme addition or by several automated methodologies. It is an ideal blending partner with any of the Millipore® IgM Anti-D FFMUs to create an IgM/IgG blended reagent.

The results of the fine specificity testing of the Millipore® monoclonal anti-D antibodies are shown below. These results were taken from the proceedings of the Third International Workshop on Monoclonal Antibodies Against Red Blood Cells and Related Antigens in Nantes, 1996. The data for MAD-2 was taken from the original study made by the creators of the clone.

Clone	II	IIIa	IIIb	IIIc	IVa	IVb	Va	VI	VII	DFR	DBT	R_0^{Har}	HMi	Howe	Carr	Casar i	Lore	Sor	1711 844
RUM-1	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+
MS-201	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+
TH-28	+	+	+	+	+	+	+	-	+	-	+	+	+	-	+	+	+	+	+
MS-26	-	+	+	+	-	-	+	+	+	+	-	-	+	+	+	+/-	+	+	+
MAD-2	+	NT	NT	NT	+	NT	(+)	-	+	-	-	-	-	NT	NT	NT	NT	NT	NT

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-D	Human IgM	RUM-1	7.2 ± 0.5	0.5–10 mg/mL	24 months	1 L Bulk	**JV-1L-BK**
						10 L Bulk	**JV-10L-BK**
Anti-D	Human IgM	MS-201	7.2 ± 0.5	1–10 mg/mL	24 months	1 L Bulk	**KU-1L-BK**
						10 L Bulk	**KU-10L-BK**
Anti-D	Human IgM	MAD-2	7.2 ± 0.5	7–22 mg/mL	24 months	1 L Bulk	**JT-1L-BK**
Anti-D	Human IgM	TH-28	7.2 ± 0.5	1–10 mg/mL	24 months	1 L Bulk	**KP-1L-BK**
						10 L Bulk	**KP-10L-BK**
Anti-D	Human IgG1	MS-26	7.2 ± 0.5	1–10 mg/mL	24 months	1 L Bulk	**KK-1L-BK**
						10 L Bulk	**KK-10L-BK**

Rh-Hr Intermediates FFMU

By offering choices of antibody for most major specificities, with subtle variations in fine specificity and avidity, we give manufacturers a range of options in formulating finished reagents or devices designed for particular applications and for differentiating their products in the market.

Anti-C IgM (clone MS-24) – KG[1,3]

KG is the established market leader for RH2 phenotyping. Like most polyclonal Anti-C reagents, it gives weaker reactions with the rare R_2R_Z type than other C positive genotypes. MS-24 agglutinates C positive red cells in the presence of C^x or C^w antigens, but testing with rare C negative, C^w positive cells has shown that it does not cross react with the C^w antigen.

Anti-C IgM (clone MS-273) – VP[2]

The potency and avidity of VP and KG are very similar; however, there are subtle differences in their fine specificities. MS-273 agglutinates C positive red cells but testing with rare C negative, C^w positive cells has shown that it does not cross react with the C^w antigen.

Anti-c IgM (clone MS-33) – VR[1,3]

Of all the antigens in the Rh Hr system, c shows the least variation. Examples of partial c are very rare; however, this antibody did react with the one example we were able to source.

Anti-c IgM (clone MS-35) – JR[1]

JR is offered as an alternative to VR. There are no known differences in potency, specificity or avidity between these two Anti-c FFMU intermediates.

Anti-c IgG (clone MS-40) -JA[2]

JA FFMU is an intermediate containing Human IgG monoclonal anti-c reactive by an indirect antiglobulin test method.

Anti-E IgM (clone MS-12) – KC[2,3]

Of the four Anti-E FFMUs, KC has the least capacity for dilution. Because of the incidence of weak and variant forms of E antigen expression, manufacturers may need to blend Millipore® Anti-E antibodies in order to formulate a balanced reagent with a broad spectrum of antigen recognition.

Anti-E IgM (clone MS-260) – KW[2,3]

KW is our most potent Anti-E and therefore has the greatest capacity for dilution. Unlike many potent IgM monoclonal antibodies, it does not react with enzyme treated antigen negative red cells.

Anti-E IgM (clone MS-80) – KX[2]

KX has a potency level that is more than KC, but less than KW.

Anti-E IgM (clone MS-258) – KT[2,3]

KT has a potency level roughly equivalent to KX.

[1] Non-diafiltered, minimal pH buffering.
[2] Diafiltered against phosphate buffered saline.
[3] Licensed with the US FDA under shared manufacturing agreement.

Anti-e IgM (clone MS-16) – KZ[1,3]

MS-16 may have the broadest specificity of the five Anti-e antibodies. Reactions are influenced by the presence or absence of the C antigen, which makes it similar to an Anti-Ce. It has been reported as giving negative reactions with RH:-34.

Anti-e IgM (clone MS-21) – KL[2,3]

MS-21 has a broad but subtly different specificity to MS-16. It reacts with some e-variants (including RH:-34, which MS-16 does not agglutinate). It has been reported as giving negative reactions with RN/RN samples.

Anti-e IgM (clone MS-63) – KQ[2,3]

KQ is the most avid and potent of the five Anti-e FFMUs. It has a narrower specificity and has been reported as giving negative reactions with RH:-19 (hrs-) cells and with some examples of RH:-34.

Anti-e IgM (clone MS-62) – JW[2]

JW's fine specificity is very similar, but not identical, to KQ.

Anti-e IgM (clone MS-69) – JX[2]

JX has reactivity which is greatly enhanced by chemical potentiation. The specificity of MS-69 is broader than MS-62 and MS-63. It has been reported that at least one example of a rare e-variant was agglutinated by this antibody and not by the other four.

Anti-C^w IgM (clone MS-110) – JP[2,3]

JP is a potent antibody which directly agglutinates red cells carrying the C^w (RH8) antigen.

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-C	Human IgM	MS-24	7.2 ± 0.5	3–12 mg/mL	24 months	125 mL Bulk	**KG-125ML-BK**
						1 L Bulk	**KG-1L-BK**
Anti-C	Human IgM	MS-273	7.2 ± 0.5	2–15 mg/mL	24 months	125 mL Bulk	**VP-125ML-BK**
						1 L Bulk	**VP-1L-BK**
Anti-c	Human IgM	MS-33	7.2 ± 0.5	TBA mg/mL	24 months	125 mL Bulk	**VR-125ML-BK**
						1 L Bulk	**VR-1L-BK**
Anti-c	Human IgM	MS-35	7.2 ± 0.5	1–15 mg/mL	24 months	125 mL Bulk	**JR-125ML-BK**
						1 L Bulk	**JR-1L-BK**
Anti-c	Human IgG	MS-40	7.0 ±0.5	10-25 mg/mL	24 Months	125 mL Bulk	**JA-125ML-BK**
						1L Bulk	**JA-1L-BK**
Anti-E	Human IgM	MS-12	7.2 ± 0.5	2–15 mg/mL	24 months	125 mL Bulk	**KC-125ML-BK**
						1 L Bulk	**KC-1L-BK**
Anti-E	Human IgM	MS-260	7.2 ± 0.5	5–16 mg/mL	24 months	125 mL Bulk	**KW-125ML-BK**
						1 L Bulk	**KW-1L-BK**
Anti-E	Human IgM	MS-80	7.2 ± 0.5	2–25 mg/mL	24 months	125 mL Bulk	**KX-125ML-BK**
						1 L Bulk	**KX-1L-BK**
Anti-E	Human IgM	MS-258	7.2 ± 0.5	4–12 mg/mL	24 months	125 mL Bulk	**KT-125ML-BK**
						1 L Bulk	**KT-1L-BK**
Anti-e	Human IgM	MS-16	7.2 ± 0.5	3–14 mg/mL	18 months	125 mL Bulk	**KZ-125ML-BK**
						1 L Bulk	**KZ-1L-BKK**
Anti-e	Human IgM	MS-21	7.2 ± 0.5	6–16 mg/mL	24 months	125 mL Bulk	**KL-125ML-BK**
						1 L Bulk	**KL-1L-BK**
Anti-e	Human IgM	MS-63	7.2 ± 0.5	1–10 mg/mL	24 months	125 mL Bulk	**KQ-125ML-BK**
						1 L Bulk	**KQ-1L-BK**
Anti-e	Human IgM	MS-62	7.2 ± 0.5	6–26 mg/mL	24 months	125 mL Bulk	**JW-125ML-BK**
						1 L Bulk	**JW-1L-BK**
Anti-e	Human IgM	MS-69	7.2 ± 0.5	6–29 mg/mL	24 months	125 mL Bulk	**JX-125ML-BK**
						1 L Bulk	**JX-1L-BK**
Anti-C^w	Human IgM	MS-110	7.2 ± 0.5	5–25 mg/mL	24 months	125 mL Bulk	**JP-125ML-BK**
						1 L Bulk	**JP-1L-BK**


Anti-c
Blood Grouping Reagent
For Further Manufacturing Use
Cell line: MS-35
Human IgM Monoclonal Antibody
JRJ1103
2011-11-04
2013-11-03
1 L
Anti-C
Blood Grouping Reagent
For Further Manufacturing Use
Cell line: MS-273
Human IgM Monoclonal Antibody
JOJ1103
2011-11-04
2013-11-03
1 L
Anti-E
Blood Grouping Reagent
For Further Manufacturing Use
Cell line: MS-12
Human IgM Monoclonal Antibody
KCJ1103
2011-11-04
2013-11-03
1 L
Anti-E
Blood Grouping Reagent
For Further Manufacturing Use
Cell line: MS-260
Human IgM Monoclonal Antibody
KWJ1103
2011-11-04
2013-11-03
1 L
Anti-e
Blood Grouping Reagent
For Further Manufacturing Use
Cell line: MS-62
Human IgM Monoclonal Antibody
JWJ1103
2011-11-04
2013-11-03
1 L
Anti-c
Blood Grouping Reagent
For Further Manufacturing Use
Cell line: MS-33
Human IgM Monoclonal Antibody
KNJ1103
2011-11-04
2013-11-03
125 mL
Anti-Cw
Blood Grouping Reagent
For Further Manufacturing Use
Cell line: MS-110
Human IgM Monoclonal Antibody
JPJ1103
2011-11-04
2013-11-03
125 mL
Anti-e
Blood Grouping Reagent
For Further Manufacturing Use
Cell line: MS-69
Human IgM Monoclonal Antibody
JXJ1103
2011-11-04
2013-11-03
125 mL

Rare Specificity Intermediates FFMU

Anti-K IgM (clone MS-56) – KO[2,3]

MS-56 is a human IgM antibody which is the established market leader for this specificity. Manufacturers wishing to make a final reagent suitable for use by the slide method should add chemical potentiators and take care to avoid a prozone phenomenon.

Anti-K IgM (clone AEK4) – KE[2]

KE FFMU also contains a human IgM Anti-K. This FFMU is offered as an alternative to KO. There is no known significant difference in potency, fine specificity or avidity between the two Anti-K FFMUs.

Anti-k IgG (clone P3A118OL67) – FA[2,3]

FA FFMU is a high titre intermediate containing human IgG monoclonal Anti-k reactive by an indirect antiglobulin test method. The reactivity of this Anti-k has been confirmed against cells of the K+,k+,Kp(a+) phenotype.

Anti-Jk^a IgM (clone MS-15) – JL[2,3]

JL is a direct agglutinating human IgM antibody. Anti-Jka reagents made from JL have generally replaced human, polyclonal, plasma-based products in the market.

Anti-Jk^b IgM (clone MS-8) – JK[2,3]

MS-8 is also a direct agglutinating human IgM antibody.

Anti-Fy^a IgG (clone P3TIM) – VL[2,3]

VL FFMU is presented as a high titre intermediate made from a human monoclonal IgG anti-Fy^a. It is capable of making a strong reacting Anti-Fy^a reagent for use in indirect antiglobulin techniques including use on gel and column IgG cards.

Anti-Fy^b IgM (clone SpA264LBg1) – FF[2,3]

This long awaited monoclonal specificity is a human IgM direct agglutinin.

Anti-M IgG (clone LM110/140) – KS[1]

KS FFMU contains a murine IgG direct agglutinating antibody. The optimal pH of an Anti-M finished reagent made from this antibody is 8.4. At pH values below 8.0 the antibody will react with NN red cells.

Anti-N IgG (clone BO3) – FD[2,3]

This murine IgG is a direct agglutinating antibody, with strong reactivity, even with heterozygous cells. Formulation or dilution of this FFMU is required to ensure non-reactivity with the “N” antigen found on GPB.

Anti-S IgM (clone MS-94) – JN[2,3]

MS-94 is a human IgM antibody. JN is a potent FFMU capable of being formulated into direct agglutinating reagents or devices.

Anti-s IgM (clone P3BER) – FE[2,3]

This human IgM antibody is a direct agglutinin, offering superior performance over monoclonal and polyclonal IgG raw materials.

Anti-Le^a IgM (clone P3N20V3) – FB[2]

Unlike most Anti-Le^a monoclonal antibodies, this strongly reactive product is of human rather than murine origin.

Anti-Le^b IgA (clone P3F234MD4) – FC[2]

FC is a potent, direct-agglutinating, human monoclonal IgA antibody. Formulation with potentiators will increase its dilutability and strengthen its reactivity with all ABO phenotypes.

[1] Non-diafiltered, minimal pH buffering.

[2] Diafiltered against phosphate buffered saline.

[3] Licensed with the US FDA under shared manufacturing agreement.

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-K	Human IgM	MS-56	7.2 ± 0.5	5–13 mg/mL	24 months	125 mL Bulk	**KO-125ML-BK**
						1 L Bulk	**KO-1L-BK**
Anti-K	Human IgM	AEK4	7.2 ± 0.5	10–30 mg/mL	24 months	125 mL Bulk	**KE-125ML-BK**
						1 L Bulk	**KE-1L-BK**
Anti-k	Human IgG	P3A118OL67	7.2 ± 0.5	2–10 mg/mL	24 months	125 mL Bulk	**FA-125ML-BK**
						1 L Bulk	**FA-1L-BK**
Anti-Fy^{a}	Human IgG	P3TIM	7.2 ± 0.5	5–15 mg/mL	24 months	125 mL Bulk	**VL-125ML-BK**
						1 L Bulk	**VL-1L-BK**
Anti-Fy^{b}	Human IgM	SpA264LBg1	7.2 ± 0.5	2–10 mg/mL	24 months	125 mL Bulk	**FF-125ML-BK**
						1 L Bulk	**FF-1L-BK**
Anti-Jk^{a}	Human IgM	MS-15	7.2 ± 0.2	6–23 mg/mL	24 months	125 mL Bulk	**JL-125ML-BK**
						1 L Bulk	**JL-1L-BK**
Anti-Jk^{b}	Human IgM	MS-8	7.2 ± 0.5	2–25 mg/mL	24 months	125 mL Bulk	**JK-125ML-BK**
						1 L Bulk	**JK-1L-BK**
Anti-Le^{a}	Human IgM	P3N20V3	7.2 ± 0.5	5–15 mg/mL	24 months	125 mL Bulk	**FB-125ML-BK**
						1 L Bulk	**FB-1L-BK**
Anti-Le^{b}	Human IgA	P3F234MD4	7.2 ± 0.5	11–40 mg/mL	24 months	125 mL Bulk	**FC-125ML-BK**
						1 L Bulk	**FC-1L-BK**
Anti-M	Murine IgG	LM110/140	7.2 ± 0.5	0.5–10 mg/mL	24 months	125 mL Bulk	**KS-125ML-BK**
						1 L Bulk	**KS-1L-BK**
Anti-N	Murine IgG	BO3	7.2 ± 0.5	0.5–10 mg/mL	24 months	125 mL Bulk	**FD-125ML-BK**
						1 L Bulk	**FD-1L-BK**
Anti-S	Human IgM	MS-94	7.2 ± 0.5	5–24 mg/mL	24 months	125 mL Bulk	**JN-125ML-BK**
						1 L Bulk	**JN-1L-BK**
Anti-s	Human IgM	P3BER	7.2 ± 0.5	10–25 mg/mL	24 months	125 mL Bulk	**FE-125ML-BK**
						1 L Bulk	**FE-1L-BK**

Anti-Human Globulin Intermediates FFMU

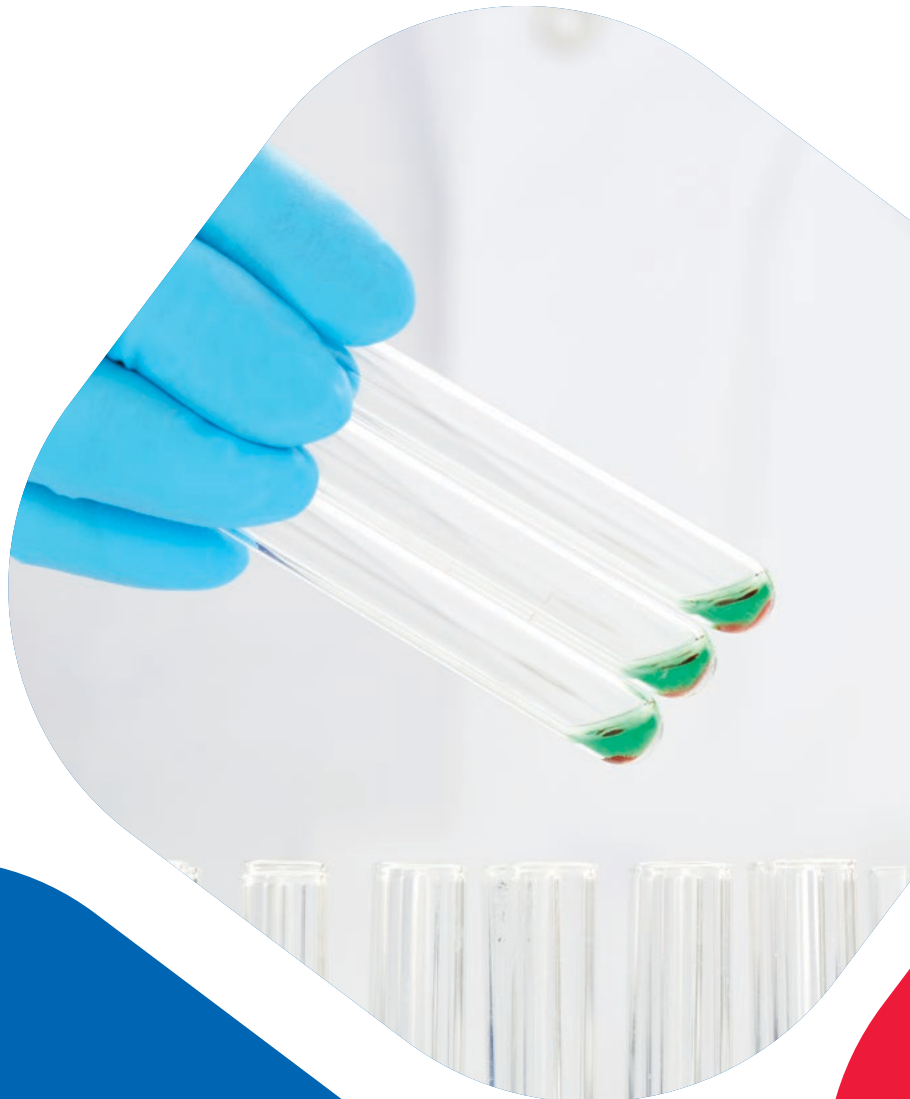
Anti-Human IgG (clone MS-278) – JZ

MS-278 is a murine IgM antibody which reacts with all four subtypes of human IgG. The FFMU is diafiltered with phosphate buffered saline.

Anti-Human C3d (clone BRIC-8) – JU

Detection of complement activation can aid in the diagnosis of autoimmune haemolytic anaemia, or the detection of some blood group allo-antibodies, particularly within the Kidd System. BRIC-8 is a murine IgM antibody that has been widely used for over 20 years as a constituent of a blended broad spectrum Anti-Human Globulin Reagent. JU is diafiltered with phosphate buffered saline and is licensed with the US FDA under shared manufacturing agreement.

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-Human IgG	Murine IgM	MS-278	7.2 ± 0.5	2–15 mg/mL	24 months	125 mL Bulk	**JZ-125ML-BK**
						1 L Bulk	**JZ-1L-BK**
Anti-Human C3d	Murine IgM	BRIC-8	7.2 ± 0.5	2–10 mg/mL	24 months	125 mL Bulk	**JU-125ML-BK**
						1 L Bulk	**JU-1L-BK**



Human IgG Monoclonal Antibodies for Research Use

The Human IgG Monoclonal Antibodies for Research Use are clarified cell culture supernatants from cell lines expressing Human IgG monoclonal blood typing antibodies that are reactive by an indirect antiglobulin test method. These products are intended for use by manufacturers wishing to make non-IVD reagents or devices such as proficiency kits, internal test controls or educational samples.

Product	Ig Type	Clone	Volume	Catalogue Number
Anti-c	Human IgG	MS-40	125 mL Bulk	**CB-125ML-RU**
Anti-C^w	Human IgG	MS-353	125 mL Bulk	**CC-125ML-RU**
Anti-E	Human IgG	MS-78	125 mL Bulk	**CD-125ML-RU**
			1 L Bulk	**CD-1L-RU**
Anti-Fy^a	Human IgG	P3TIM	125 mL Bulk	**CE-125ML-RU**
Anti-K	Human IgG	MS-59	125 mL Bulk	**CF-125ML-RU**

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